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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,070	08/06/2001	Hong Jin	7682-059-999	1768

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/923,070	JIN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- **Th MAILING DATE of this communication appears on th cover sheet with th correspond nce address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1,4,and 5, drawn to isolated infectious RSV particles that comprise an RSV genome or antigenome with a least one lethal deletion in the M2-ORF1 gene, classified in class 435, subclass 235.1.
 - II. Claims 2,4, and 5, drawn to isolated infectious RSV particles which comprise a chimeric RSV genome or antigenome encoding antigenic polypeptides of both RSV-A and RSV-B, classified in class 435, subclass 235.1.
 - III. Claims 3,4, and 5, drawn to RSV particles with attenuated phenotypes comprising an RSV genome or antigenome with an L gene mutation, classified in class 435, subclass 236.
 - IV. Claims 6-11, drawn to recombinant RNA with a binding site specific for RSV RNA-directed RNA polymerase operatively linked to a RSV RNA containing a deletion in the M2-ORF1 or M2-ORF2, and a heterologous sequence comprising the reverse complement a coding sequence, classified in class 435, subclass 235.1.
 - V. Claim 12, drawn to a method of producing a chimeric RSV, classified in class 435, subclass 235.1.
 - VI. Claims 13-20, drawn to vaccines comprising chimeric RSV, the genome of which comprises the reverse complement of an mRNA coding sequence operatively

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linked to a RSV polymerase binding site and a pharmaceutically acceptable carrier, classified in class 435, subclass 235.1.

- VII. Claims 21-24, drawn to attenuated genetically engineered RSV containing at least one modified gene sequence so at least some defective particles are produced during each round of viral replication, classified in class 435, subclass 236.

For Group IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and, if Group IV is elected, then election is also required to one of inventions (IV-1) and (iv-2) and to one of inventions (IV-A) or (IV-B). These subgroups represent the recombinant RNA of Group IV wherein:

- (IV-1) the RSV RNA has a deletion in M2-ORF1;
- (IV-2) the RSV RNA has a deletion in M2-ORF2;

- (IV-A) the heterologous sequence is derived from the genome of a virus other than RSV;
and
- (IV-B) the heterologous sequence is derived from the genome of another strain of RSV.

For Group VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and, if Group VI is elected, then election is also required to one of inventions (VI-1)- (VI-6). These subgroups represent the vaccine of Group VI wherein:

- (VI-1) the mRNA sequence encodes a mutated SH gene;
- (VI-2) the mRNA sequence encodes a mutated L gene;
- (VI-3) the mRNA sequence encodes a mutated NS1 gene;
- (VI-4) the mRNA sequence encodes a mutated M2 gene;
- (VI-5) the mRNA sequence encodes both the G and F genes of both RSV-A and RSV-B;
and
- (VI-6) the vaccine encodes a heterologous gene.

For Group VII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and, if Group VII is elected, then election is also required to one of inventions (VII-1) or (VII-2). These subgroups represent the attenuated virus of Group VII wherein:

- (VII-1) the sequence modified is a non-coding region of that results in down-regulation of synthesis of a viral gene; and

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- (VII-2) the sequence modified is a gene sequence encoding at least one insertion, deletion, or substitution of an amino acid residue or epitope.

The inventions are distinct, each from the others, for the following reasons:

2. The inventions of Groups I-IV, VI, and VII, and each of the subgroups of Groups IV, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to recombinant RSV or RSV RNA that comprise different gene mutations. The mutation of different genes result in different mutated proteins, or different proteins altogether. As the inclusion of, or mutation of, different proteins result in inventions with different functions or different modes of operation, each of the different inventions is distinct from the others.
3. The inventions of Group V and of Groups I, II, III, VI, and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, as the method of making may be used to make any of the identified products, the method is distinct from any one of them.

Examiner's Notes

4. The examiner would like to point out to the applicant what appears to be an error in claim 2. On line 3 of the claim, it describes the claimed RSV particle as having a chimeric antigenome

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encoding antigenic polypeptides of both “RVS-A and RSV-B.” It appears that the applicant intended the phrase to read “RSV-A and RSV-B.”

5. Although no rejection is being made at this time, the examiner would like to point out an error in claim 12 that renders the claim indefinite under 35 U.S.C. 112 ¶1. The claim requires that a host cell be cultured in the absence of expression of M2-ORF. The claim does not identify which ORF of the M2 region is not being expressed. If the applicant elects Group V above, the claims will be rejected under 35 U.S.C. 112 ¶ 1 for indefiniteness.

6. This application contains several linking claims. Although most linking claims have been included in the same Group as the linked inventions, claim 21 has been included in the same Group as all of the claims which it links. This claim links the claims of Group I, Group III, Group IV, subgroups (VI-1)-(VI-4) as well as the other claims of Group VII. Claim 23 also acts as a linking claim for claims of other groups.

In accordance with PTO linking claim practice, as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

7. Applicant’s attention is hereby directed to the following is a recitation of M.P.E.P.

§821.04 regarding the restriction of claims to a product and processes of using the product,

Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

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Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an allowed product claim**. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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Conclusion

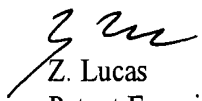
8. Because these inventions are distinct for the reasons given above, because of recognized divergent subject matter and different classifications, and because the literature searches required for each of the identified Groups is not required for other Groups, restriction for examination purposes as indicated is proper.

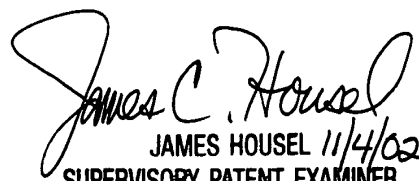
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
November 1, 2002


JAMES HOUSEL 11/4/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600